

### REMARKS

Claims 1-26, 29-36, 38, 39 and 42-54 are pending in the subject application. Claims 1, 42, 44-46, 48-49 and 52-54 have been amended herein. Claim 47 has been canceled without prejudice. The amendments to the claims are supported by the originally filed disclosure.

#### 1. Specification

The disclosure is objected to under 37 CFR 1.71. The Office points to claims 1, 16, 26, 29, 42 and 44-48 and the embodiment of figures 2 and 3 and asserts that

The embodiment of figures 2 and 3, as described in the specification and shown in the drawings on 12/17/03, is incapable of being used. It is unclear from the specification and drawings how a device for placing **a proximal portion of a penetrating member** in a target area after **the apparatus is positioned in proximity to an entry point of an object containing the target area** by a manipulation device, and where **the manipulation device can position the apparatus in proximity to the entry point of the object containing the target area**. Since the manipulation device as best seen in fig. 3 of the application clearly indicates that the apparatus is **distal** to the entry point of the object containing the target area (distal to element 154b).

Applicants respectfully traverse.

Applicants teach, as set out in the claims and specification, an apparatus for placing a proximal portion of a penetrating member 50 in a target area. The apparatus includes a first arm 120 in connection with a first drive mechanism. The first arm 120 supports the penetrating member 50. The apparatus is in connection with a manipulation device that positions the apparatus, and, thus, the penetrating member 50, in proximity to an entry point of an object containing the target area. The apparatus may further include a second arm 140 in connection with a second drive mechanism (independent claims 29, 42 and 44-46).

Applicants respectfully submit that the claims and specification state that the manipulation device positions the apparatus in proximity to the entry point. The Office's assertion that the apparatus is distal the entry point is not understood. Proximal and distal are

relative terms and, as used herein and as described by Applicants, "in proximity" means that the apparatus (which includes the arm which supports the penetrating member) is moved from a first location to a second location that is in proximity to the entry point so that the proximal portion of the penetrating member may be placed into the target site. For example, the first arm 120 may be moved, when viewing the device in Figs. 1-3, towards the right. Thus, the first arm would move from a direction where it is close to the body of the housing 110 to a direction where it is spaced a distance from the body of the housing 110. Thus, if the entry point is to the right of the device (to the right of the body of the housing 110), then the arm can be moved away from the body of the housing to the right towards the entry point and, thus, in proximity to the target site.

In view of the above, it is respectfully submitted that the claims and specification are clear as they appear. Reconsideration and withdrawal of the objection is respectfully requested.

## 2. 35 U.S.C. §112 Rejections

Claims 1-15, 17-26, 29-39 and 42-54 are rejected under 35 U.S.C. §112, second paragraph. In view of the description above regarding the Specification objection, Applicants respectfully request reconsideration and withdrawal of the rejection.

## 3. 35 U.S.C. §102 Rejection

Claims 1, 16, 26, 29, 42 and 46 are rejected under 35 U.S.C. §102(b) as being anticipated by Ng (5,820,623). Applicants respectfully traverse.

Applicants claim, in claim 1, an apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area by a manipulation device. The apparatus comprises a first arm being configured and arranged to rotatably support the penetrating member, a first drive mechanism coupled to the first arm, and a second drive mechanism coupled to the penetrating member. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position. The second

drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member.

Ng describes an articulated arm that supports and positions medical tools in space. According to Ng, the arm provides three degrees of linear freedom: 8 (X), 7 (Y) and 6 (Z), plus a rotational swing 5 (R) (see col. 8, line 4 – col. 9, line 2 and Fig. 13). Rotational swing 5 (R), as clearly shown in Fig. 13 does not cause the medical tool to rotate about a long axis of the penetrating member, but rather causes the medical tool to swing about as shown. None of these movement directions includes rotation of the medical tool 179 about its long axis.

Thus, Ng does not teach or suggest a device configured and arranged to rotatably support the penetrating member, wherein a drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member.

Accordingly, applicants submit that claim 1 is patentable over Ng. Claims 49 and 52 depend from claim 1 and, likewise, are patentable over Ng. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants claim, in claim 16, an apparatus for placing a proximal portion of a penetrating member in a target area comprising a first arm configured and arranged to support the penetrating member, a first drive mechanism coupled to the first arm and including a linear guide. The first guide mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area. The linear guide is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates.

The Office asserts that Ng describes a first drive mechanism 302 that includes a linear guide, pointing to col. 5, lines 1-6. Applicants respectfully disagree. Drive mechanism 302 is an arch drive assembly that moves the carriage 137 in an arcuate path (see col. 4, lines 45-50), not a linear path. Drive mechanism 302 does not nor could it include a linear guide because such a guide would prevent the drive mechanism from moving the carriage 137 (which holds the medical device) in an arcuate path as required.

Accordingly, Applicants respectfully submit that claim 16 is patentable over Ng. Claims 2-15 and 17-25 depend from claim 16 and, likewise, are patentable over Ng. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants claim, in claim 26, an apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area. The apparatus comprises a first arm configured and arranged to rotatably support the penetrating member, a first drive mechanism coupled to the first arm, and a second drive mechanism coupled to the penetrating member and comprising a gear member secured to the penetrating member. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area. The second drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member. The second drive mechanism comprises a gear member secured to the penetrating member and is mechanically coupled to a motor such that operation of the motor causes the penetrating member to rotate about the long axis.

As set forth above with relation to claim 1, Ng does not teach or suggest a device configured and arranged to rotatably support the penetrating member, wherein a drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member.

Accordingly, claim 26 is patentable over Ng. Claims 27-28 depend from claim 26 and, likewise, is patentable over Ng. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants claim, in claim 29, an apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area. The apparatus comprises a first arm configured and arranged to rotatably support the penetrating member, a first drive mechanism coupled to the first arm, a second arm coupled to the first drive mechanism, and a second drive mechanism coupled to the penetrating member. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area. The first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates. The second arm coupled to the first drive mechanism so that the first arm translates towards the second arm. The second drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member.

As set forth above with relation to claim 1, Ng does not teach or suggest a device configured and arranged to rotatably support the penetrating member, wherein a drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member. As further set forth above with relation to claim 16, Ng does not teach or suggest a first drive mechanism including a linear guide.

Further, Applicants respectfully submit that Ng does not teach or suggest a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm. The

Office asserts that Ng describes a first arm 124 and a second arm 125. However, element 125 is merely an extension of arch 124 and is described as a stiffener that acts to strengthen the arch support 300 and give bearing surfaces (col. 7, lines 28-30). Thus, Applicants respectfully submit that Ng does not teach or suggest a second arm.

Accordingly, claim 29 is patentable over Ng. Claims 30-36, 38-41, 50 and 53 depend from claim 29 and, likewise, are patentable over Ng. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants claim, in claim 42, an apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body. The apparatus comprises a first arm configured and arranged to rotatably support the needle, a first drive mechanism coupled to the first arm and including a linear guide, a second arm coupled to the first drive mechanism and including a guide mechanism. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area. The second arm is coupled to the first drive mechanism so that the first arm translates towards the second arm. The linear guide is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates. The second drive mechanism is configured and arranged so as to cause the needle to rotate about a long axis of the needle.

As set forth above with relation to claim 1, Ng does not teach or suggest a device configured and arranged to rotatably support the penetrating member, wherein a drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member. As further set forth above with relation to claim 16, Ng does not teach or suggest a first drive mechanism including a linear guide. Further, as set forth

above with relation to claim 29, Ng does not teach or suggest a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm.

Accordingly, claim 42 is patentable over Ng. Claims 43, 51 and 54 depend from claim 42 and, likewise, are patentable over Ng. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants claim, in claim 44, an apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body. The apparatus comprises a first arm configured and arranged to rotatably support the needle, a first drive mechanism coupled to the first arm, a second arm coupled to the first drive mechanism and including a guide mechanism in which the needle is moveably received, a second drive mechanism coupled to the needle. The first drive mechanism includes a screw, a bi-directional motor and a linear guide. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area. The second drive mechanism is configured and arranged so as to cause the needle to rotate about a long axis of the needle.

As set forth above with relation to claim 1, Ng does not teach or suggest a device configured and arranged to rotatably support the penetrating member, wherein a drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member. As further set forth above with relation to claim 16, Ng does not teach or suggest a first drive mechanism including a linear guide. Further, as set forth above with relation to claim 29, Ng does not teach or suggest a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm.

Accordingly, claim 44 is patentable over Ng. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants claim, in claim 45, an apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body. The apparatus comprises a first arm configured and arranged to rotatably support the needle, a first drive mechanism coupled to the first arm, a second arm coupled to the first drive mechanism and including a guide mechanism in which the needle is moveably received, a second drive mechanism coupled to the needle. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area. The second arm is coupled to the first drive mechanism so that the first arm translates towards the second arm. The second drive mechanism is configured and arranged so as to cause the needle to rotate about a long axis of the needle.

As set forth above with relation to claim 1, Ng does not teach or suggest a device configured and arranged to rotatably support the penetrating member, wherein a drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member. As further set forth above with relation to claim 16, Ng does not teach or suggest a first drive mechanism including a linear guide. Further, as set forth above with relation to claim 29, Ng does not teach or suggest a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm.

Accordingly, claim 45 is patentable over Ng. Reconsideration and withdrawal of the rejection is respectfully requested.



Applicants claim, in claim 46, a method for localizing a proximal portion of a penetrating member in a target area of a body comprising: supporting the penetrating member from a first arm, positioning the first arm with respect to the body so a long axis of the penetrating member passes through the target area; linearly translating the first arm from an initial position to any of a number of other positions spaced from the initial, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area; and rotating the penetrating member about the long axis thereof.

As set forth above, Ng does not teach or suggest a device wherein the penetrating member may be rotated about a long axis. Accordingly, claim 46 is patentable over Ng. Claim 48 depends from claim 46 and, likewise, is patentable over Ng. Reconsideration and withdrawal of the rejection is respectfully requested.

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U.S.S.N. : 09/943,751  
Page 24 of 24

**CONCLUSION**

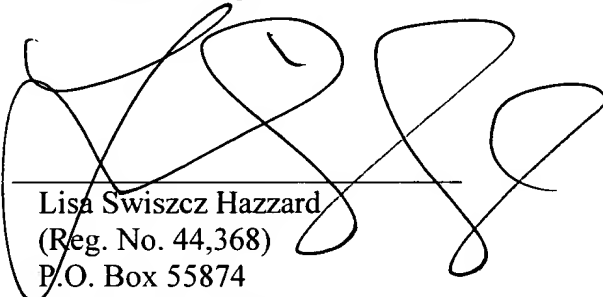
It is respectfully submitted that the subject application is in a condition for allowance.  
Early and favorable action is requested.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any  
excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account  
No. **04-1105**.

Respectfully submitted,  
Edwards & Angell, LLP

Date:

By:



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